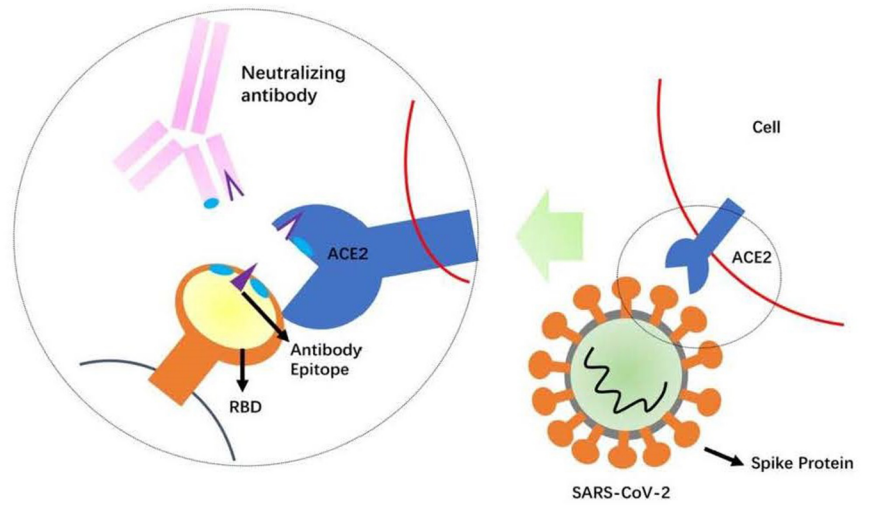


Made in the USA
CE Marked

Results in 10 min

Fingerstick
Blood or
Serum



QuickProfile™ SARS-CoV-2 Neutralizing Antibody Test Card



The Cut-off value of QuickProfile™ SARS-CoV-2 Neutralizing Antibody Test Card was calibrated against 1st WHO International Standard, 20/136, at 100 BAU/mL.

QuickProfile™ SARS-CoV-2 Neutralizing Antibody

Analytical Sensitivity: QuickProfile™ SARS-CoV-2 Neutralizing Antibody Test Card has set the cut-off at 100 Binding Antibody Unit (BAU)/mL of 1st WHO International Standard, 20/136.

1 st WHO Standard 20/136	Number of samples	Number of High Level NAb	Number of Low Level NAb	Number of Negative
0 BAU/mL	20	0	0	20
50 BAU/mL	20	0	20	0
100 BAU/mL	20	20	0	0
150 BAU/mL	20	20	0	0
1000 BAU/mL	20	20	0	0

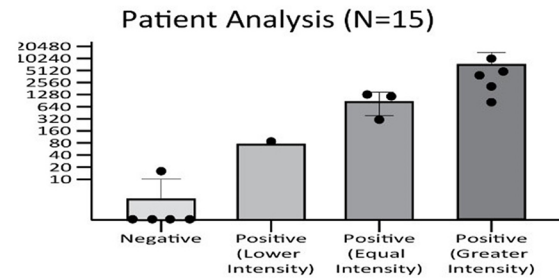
Forty-eight (48) fully vaccinated samples were followed at 3 weeks after the first dosage and 2 weeks after the second dosage to monitor the level of antibodies.

Vaccine	Number of samples	Dosage	Number of High level NAb	Number of low level NAb	Number of negative
Moderna	4	1st	2	1	1
		2nd	4	0	0
Pfizer	13	1st	1	11	1
		2nd	13	0	0
SinoVac	31	1st	2	13	16
		2nd	26	5	0

Accuracy: Seventy-five (75) samples collected from healthy people prior to December 2019, thirty (30) samples of convalescent serum from infected people and ninety-nine (99) samples from fully vaccinated individuals with various vaccines were tested. The results of convalescent samples were compared with an EUA approved surrogate virus neutralization test (sVNT) kit. The cut-off the sVNT test kit is set at 30% of inhibition of RBD protein binds to ACE-2. All twenty-three (23) samples that have virus inhibition rate 28% or higher showed high antibody level results on our kit..

The correlation of QuickProfile™ SARS-CoV-2 Neutralizing Antibody Test results with Plaque Reduction Neutralization Test (PRNT) was measured on fifteen (15) patient samples including five (5) samples without SARS-CoV-2 infection and eleven (11) samples that had natural infection. In this study, samples that have PRNT50 titer higher than 254 all show equal or higher than cut-off level results

	Number of samples	Number of high level NAb	Number of low level NAb	Number of negative
Pfizer Vaccinated Sample	31	30	1	0
Moderna Vaccinated Sample	32	31	1	0
SinoVac Vaccinated Sample	31	26	5	0
Janssen (J&J) Vaccinated Sample	5	4	1	0
Convalescent Sample (Inhibition ≥ 28%)	23	23	0	0
Convalescent Sample (Inhibition < 28%)	7	1	6	0
Healthy Sample	75	0	1	74



Lumiquick Neutralizing Ab Test Score

RESULT INTERPRETATION

For detailed guidance on interpretation consult the IFU

POSITIVE
High Level Low Level

NEGATIVE

INVALID



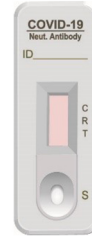
All lines are present



Test line is absent



Control and/or Reference line is absent.
The test should be repeated



Ordering Information:

QuickProfile™ SARS-CoV-2 Neutralizing Antibody Test Card - Code: 71108N - 25 Tests per Kit